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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,576	05/21/2007	Hanae Kaku	SHIMIZU-13111	3078

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EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,576	KAKU ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 14-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-10, and 14-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 03/23/09 in reply to the Office action of 12/15/08 has been entered. Claims 1-2, 10 and 14 have been amended. New claims 17-42 are added

Claims 1-42 are pending.

This application contains claims 3 and 11-13 drawn to an invention nonelected with traverse in the reply filed on 11/10/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-2, 4-10, and 14-42 are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and/or upon further consideration.

New Matter Rejection

Claims 25, 27-34, and 36-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims also recite a DNA sequence encoding a protein that has from 95% to 100% identity with SEQ ID NO: 2. However, support for the limitations "95% to 100%" cannot be found in specification or in the claims as originally filed. The specification

does provide support for "95%, 100%" but does not provide support for the range limitation "95% to 100" which includes 96%, 97%, 98% and 99%. Therefore, the limitation "95% to 100%" is considered to be new matter. Therefore, Applicant is requested to point to support for the phrases in the originally filed application or to delete the NEW MATTER in response to this rejection.

Claim Rejections - 35 USC § 102

Claims 17-33 are rejected under 35 U.S.C. 102(e) as being anticipated by LaRosa et al (US 20040123343 A1, filed 05/14/03). This rejection is repeated for the reasons of record as set forth in the last Office action of 12/15/08. Applicant's arguments filed 03/23/09 have been considered but are not deemed persuasive.

Applicant argues that La Rosa discloses a DNA sequence with 1399 nucleotides that is 100% identical to Applicant's SEQ ID NO: 1 but is only among 102,483 sequences having one of at least forty functions listed in the specification and which may be used produce transgenic plants. Applicant asserts that La Rosa does not provide an enabling disclosure and cannot be used as an anticipatory prior art. Applicant cites Elan Pharmaceuticals, Inc. v. *Mayo Foundation for Medical Education and Research* (Fed. Cir. 2003) to support this position (response, pp. 15-15).

These are not found persuasive because La Rosa teaches an isolated DNA that is identical to Applicant's SEQ ID NO: 1 and 3, and does provide enablement for how to use said DNA sequences to produce transgenic plants with improved properties including increased disease resistance. The use of a readily available DNA sequence to

transform a plant does not constitute an undue experimentation because at the time Applicant's application was filed, one of ordinary skill in the would be able to transform a plant using the various plant transformation methods known in the prior art and also disclosed in La Rosa (see, for example, paragraphs 0075-0078). In the case of Elan Pharmaceutical, the issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's transgenic mouse without undue experimentation. Unlike the situation in the instant application, one of ordinary skill in the would be able to transform a plant with any of the 102,482 unmodified DNA sequences with complete open reading frame and encoding a full length protein sequence to produce a transgenic plants without undue experimentation.

The MPEP 2121 states "[a] prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention. See also Impax Labs. Inc. v. Aventis Pharm . Inc., 468 F.3d 1366,1383, 8 USPQ2d 1001, 1013 (Fed. Cir. 2006) which teaches that proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation. The MPEP further states [a] reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

With regard to Applicant's arguments regarding the lack of correlation between that disclosed sequences and disease resistance function in La Rosa, it is noted that no function need be disclosed by the reference because the prior art DNA is identical to Applicant's DNA and the reference also teaches how to make the DNA and how to use it for plant transformation. See the MPEP Section 2122, which states "[i]n order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992) (The application claimed compounds used in ophthalmic compositions to treat dry eye syndrome. The examiner found a printed publication which disclosed the claimed compound but did not disclose a use for the compound. The court found that the claim was anticipated since the compound and a process of making it was taught by the reference. The court explained that "no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." 964 F.2d at 1124, 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.) Therefore, for all the reasons discussed above and in the last Office action, the rejection is proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-10, and 14-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over La Rosa (US 20040123343 A1, filed 05/14/03).

La Rosa et al teach an isolated DNA having 100% sequence identity to Applicant's SEQ ID NO: 1 and encoding a polypeptide having 100% sequence identity with Applicant's SEQ ID NO: 2 and 4 a vector comprising said DNA, transformed plant/cells/seed, and a method of transforming plants including rice with said DNA to produce transgenic plants/cells. At paragraph [0020], La Rosa states that the polynucleotides have been isolated to use in the generation of transgenic plants with modified properties including disease resistance. The chitin oligosaccharide elicitor binding and blast disease resistance activity of SEQ ID NO: 2 or 4 are inherent properties.

La Rosa et al do not teach a DNA sequence lacking the signal sequence encoding amino acids 1-28 of SEQ ID NO: 2. However, it would have been obvious to one of ordinary skill in the art to use the DNA sequence with or without signal

sequence. In addition, signal sequence is a regulatory region and is not required for the disease resistance activity of the encoding region. One of ordinary skill in the art would not expect functional differences between SEQ ID NO: 1 and SEQ ID NO: 3 since they both encode the same polypeptide with or without the N-terminal region, respectively. Applicant has not shown any unexpected results with the DNA sequence of SEQ ID NO: 1 encoding SEQ ID NO: 2 which could not be obtained with the DNA sequence of SEQ ID NO: 3 encoding SEQ ID NO: 4. Therefore, the claimed invention as whole was a prima facie obvious as stated in the last Office action.

Remarks

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
6/21/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638